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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,959	02/12/2002	Avery J. Evans	SPEC-6150	6989

7590 05/19/2005

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EXAMINER

RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No.	Applicant(s)	
	10/074,959	EVANS ET AL.	
	Examiner	Art Unit	
	Anu Ramana	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 and 29-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 4-10, 12, 14, 15-20, 29 and 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Box et al. (US 4,832,692).

Box et al. disclose a syringe assembly or system having a plunger assembly including a shaft with a threaded portion 60, a hand knob 62, a dispenser hub assembly (hand grip 46, collar 15 with an internally threaded portion), a transparent hollow tube 11, a trigger 44 and a spring 45 (Figs. 1-5, col. 3, lines 31-68, col. 4, lines 1-59, col. 5, lines 10-68 and col. 6, lines 1-38).

The introductory statement and all other functional statements of intended use, namely, "for percutaneous delivery of bone cement," "for percutaneous delivery of bone cement during the surgical procedure," "for controlled displacement of bone cement" have been carefully considered but are deemed not to impose any structure on the claims distinguishable over the Box et al. reference.

Claims 1-2, 4-5, 10, 12-19, 21-25 and 29-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Preissman (US 6,383,190).

Preissman discloses a system for delivery of bone cement including: a plunger assembly with a shaft having a threaded middle section 96 and a handle 92 attached to a first end of the shaft; a dispenser hub assembly having a collar (94d) with an internally threaded portion; a handle (92) attached to the shaft; a hand-grip (64, 75) attached to

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the collar; a syringe or "hollow tube" 152 removably engaged with the collar; a cannula 10; a stylet 1'; and a tubing assembly 70 with luer fittings at both ends (Figs. 7-9, 13, 15, 18, col. 8, lines 20-67, col. 9, col. 10, lines 1-36, col. 13, lines 14-67 and col. 14, lines 1-10).

Regarding claims 3 and 30, Preissman discloses that an enlarged introduction section may be provided in the barrel 152 of the syringe to aid in introduction of the plunger without forming a seal (Fig. 21 and col. 17, lines 9-65).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 30 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Box et al. (US 4,832,692) in view of Thornhill et al. (US 6,019,765).

Box et al. discloses all elements of the claimed invention except for a funnel-shaped opening at a distal end of member 11. See discussion for claim 1.

Thornhill et al. teach providing a funnel-shaped opening at a distal end of syringe (Fig. 5) to facilitate filling the syringe with material (Fig. 5 and col. 4, lines 19-22).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a funnel-shaped opening to a distal end of the Box et al. syringe, as taught by Thornhill et al. for ease of placement of material within the Box et al. syringe.

Claim 11 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Box et al. (US 4,832,692), as applied to claim 1.

Box et al. discloses the claimed invention except for a syringe volume of 10cc. It would have been an obvious matter of design choice to have made the Box et al.

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syringe with a volume of 10 cc, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

Claim 13 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Box et al. (US 4,832,692), as applied to claim 1, in view of LeVeen et al. (US 4,312,343).

Box et al. disclose all elements of the claimed invention except that the syringe has a plurality of graduations.

LeVeen et al. teach making a syringe of a transparent material with a plurality of graduations to facilitate visual observation of the syringe contents and measurement of the piston movement (col. 2, lines 29-44).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the Box et al. syringe with a plurality of graduations, as taught by LeVeen et al. for visual observation of the syringe contents and measurement of piston movement.

Claim 14 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Box et al. (US 4,832,692), as applied to claim 1, in view of Fischer (US 5,603,701).

Box et al. disclose all elements of the claimed invention except that hand knob 62 is ergonomically shaped.

Fischer teaches knob 80 of a syringe apparatus to be shaped to facilitate ease of gripping and manipulation by the user with a minimal amount of wrist rotation (col. 5, lines 46-54).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided an ergonomically shaped hand knob in the Box et al. syringe apparatus, as taught by Fischer for ease of manipulation by the user.

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Claim 14 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Preissman (US 6,383,190), as applied to claim 1, in view of Fischer (US 5,603,701).

Preissman discloses all elements of the claimed invention except that handle 92 is ergonomically shaped.

Fischer teaches handle 80 of an apparatus to be shaped to facilitate ease of gripping and manipulation by the user with a minimal amount of wrist rotation (col. 5, lines 46-54).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided an ergonomically shaped handle in the Preissman apparatus, as taught by Fischer for ease of manipulation by the user.

Claims 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhatnagar et al. (US 6,395,007) in view of Preissman (US 6,383,190).

Bhatnagar et al. disclose a kit having a cement delivery means 42, a tubing assembly 44 removably attached to the cement delivery means 42, a cannula 12, a stylet 2, a hammer and a forceps (Fig. 4, col. 5, lines 31-66, col. 6, lines 1-35, col. 8, lines 45-59, col. 9, lines 46-67, col. 10, lines 1-26 and lines 55-61).

Bhatnagar et al. further disclose that any cement delivery means could be used (col. 9, lines 7-17).

Bhatnagar et al. disclose all elements of the claimed invention except for a cement delivery means including a plunger assembly and a dispenser hub assembly disposed around the shaft.

Preissman teaches a cement delivery means having a plunger assembly with a shaft and a handle attached to an end of the shaft and a dispenser hub assembly around the shaft (see previous discussion).

It would have been obvious to one of ordinary skill in the art at the time the invention was made have substituted a cement delivery means as, for example, taught by the Preissman reference for the cement delivery means in the Bhatnagar et al. kit wherein so doing would amount to mere substitution of one functionally equivalent

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structure for another within the same art and the selection of any of these devices would work equally well in the claimed device.

Conclusion

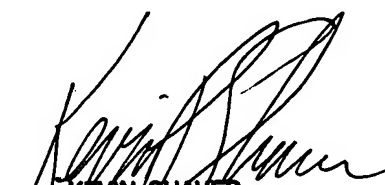
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR 
May 14, 2005


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